UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

IN RE ZETIA (EZETIMIBE) ANTITRUST LITIGATION	
This document relates to:	MDL No. 2:18-MD-2836
Direct Purchaser Actions	**Filed Under Seal**

DIRECT PURCHASER PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR CLASS CERTIFICATION

I. INTRODUCTION

More than three dozen district courts, including this one,[1] have certified direct purchaser classes mirroring the class proposed in this case for purposes of trial or settlement.[2]

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[1] *Am. Sales Co., LLC v. Pfizer, Inc.*, No. 2:14-cv-361, 2017 WL 3669604 (E.D. Va. July 28, 2017) ("*Celebrex*"), *adopted*, No. 2:14-cv-361, 2017 WL 3669097 (E.D. Va. Aug. 24, 2017); *In re Zetia Antitrust Litig.*, No. 2:18-cv-2836 (E.D. Va. Oct. 1, 2019) ECF No. 668, *adopted*, No. 2:18-cv-2836 (E.D. Va. Nov. 5, 2019) ECF No. 711 (settlement class). Unless indicated otherwise, ECF references herein are to those entered in this multi-district litigation.

[2] For Trial: *In re Suboxone (Buprenorphine Hydrochloride & Nalaxone) Antitrust Litig.*, No. 13-md-2445, 2019 WL 4735520 (E.D. Pa. Sept. 27, 2019) *Rule 23(f) pet. to appeal granted* No. 19-3640 (3d Cir. Nov. 4, 2019); *In re Intuniv Antitrust Litig.*, No. 16-cv-12653, 2019 WL 4645502 (D. Mass. Sept. 24, 2019); *In re Niaspan Antitrust Litig.*, No. 13-md-2460, 2019 WL 3816829 (E.D. Pa. Aug. 14, 2019) *In re Loestrin 24 Fe Antitrust Litig.*, No. 13-md-2472, 2019 WL 3214257 (D.R.I. July 2, 2019); *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152 (S.D.N.Y. 2018); *In re Lamictal Indirect Purchaser Antitrust Litig.*, No. 12-cv-00995, 2018 WL 6567709 (D.N.J. Dec. 12, 2018), *Rule 23(f) pet. to appeal granted*, No. 18-8061 (3d. Cir. Mar. 3, 2019); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. CV 14-md-02503, 2017 WL 4621777 (D. Mass. Oct. 16, 2017); *In re Lidoderm Antitrust Litig.*, No. 14-md-2521, 2017 WL 679367 (N.D. Cal. Feb. 21, 2017); *In re Nexium (Esomeprazole) Antitrust Litig.*, 296 F.R.D. 47 (D. Mass. 2013); *In re Prograf Antitrust Litig.*, No. 11-cv-10344, 2013 WL 2395083 (D. Mass. Apr. 23, 2013); *In re Wellbutrin XL Antitrust Litig.*, No. 08-cv-2431, 2011 WL 3563385 (E.D. Pa. Aug. 11, 2011); *In re Neurontin Antitrust Litig.*, No. 02-cv-1390, 2011 WL 286118 (D.N.J. Jan. 25, 2011); *Am. Sales Co. Inc. v. SmithKline Beecham Corp.*, 274 F.R.D. 127 (E.D. Pa. 2010) ("*Flonase*"); *In re Wellbutrin SR Direct Purchaser Antitrust Litig.*, No. 04-cv-5525, 2008 WL 1946848 (E.D. Pa. May 2, 2008); *Teva Pharm. USA, Inc. v. Abbott Labs.*, 252 F.R.D. 213 (D. Del. 2008) ("*TriCor*"); *In re K-Dur Antitrust Litig.*, No. 01-cv-1652, 2008 WL 2699390 (D.N.J. Apr. 14, 2008), *aff'd*, 686 F.3d 197 (3d Cir. 2012); *vacated on other grounds*, 133 S. Ct. 2849 (2013), *class certification holding reinstated*, *In re K-Dur Antitrust Litig.*, No. 10-cv-2077, 2013 WL 5180857 (3d Cir. Sept. 9, 2013); *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07-cv-7343 (HB), 2008 WL 11399716 (S.D.N.Y. Apr. 8, 2008); *In re Nifedipine Antitrust Litig.*, 246 F.R.D. 365 (D.D.C. 2007); *Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd.*, 246 F.R.D. 293 (D.D.C. 2007) ("*Ovcon*"); *In re Relafen Antitrust Litig.*, 218 F.R.D. 337 (D. Mass. 2003); *In re Buspirone Antitrust Litig.*, 210 F.R.D. 43 (S.D.N.Y. 2002); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297 (E.D. Mich. 2001); *Meijer, Inc. v. Abbott Labs.*, No. 07-cv-5985, 2008 WL 4065839 (N.D. Cal. Aug. 27, 2008) ("*Norvir*") (certifying class challenging market exclusion of less-expensive drugs); *J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc.*, 225 F.R.D. 208 (S.D. Ohio 2003) (certifying class alleging suppression of entry of near-identical brand drug) ("*Premarin*").

For Settlement: *In re Aggrenox Antitrust Litig.*, No. 3:14-md-2516, 2017 WL 4278788 (D. Conn. Sept. 19, 2017); *In re Asacol Antitrust Litig.*, No. 1:15-cv-12730, 2017 WL 4118967 (D. Mass. Sept. 14, 2017); *In re Prandin Direct Purchaser Antitrust Litig.*, No. 2:10-cv-12141, 2014

These courts have held that where a brand drug company's anticompetitive conduct impairs generic competition, that misconduct inflicts predictable, market-wide harm on direct purchasers in the form of overcharges. This Court recognized this fact when it certified a litigation class in the *Celebrex* generic drug delay case, where a similar set of direct purchasers alleged that the manufacturer of branded Celebrex fraudulently obtained a patent for that drug,[3] and in this case, certifying a class of these same direct purchasers when they settled their claims against defendant Par Pharmaceuticals. As in these prior instances, this case focuses on the misconduct of the *defendants*—here Merck, Glenmark, and Par[4]—and the class-wide impact of that misconduct.

Here, the direct purchaser class plaintiffs[5] seek to certify a class of: All persons or

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WL 8335997 (E.D. Mich. Oct. 2, 2014); *In re Skelaxin (Metaxalone) Antitrust Litig*., MDL No. 2343, 2014 WL 11669877 (E.D. Tenn. Apr. 30, 2014); *Mylan Pharm.*, *Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-cv-3824, 2014 WL 631031 (E.D. Pa. Feb. 18, 2014) ("*Doryx*"); *Rochester Drug Co-Operative*, *Inc. v. Braintree Labs*., *Inc.*, No. 07-cv-142, 2012 WL 12910047 (D. Del. Feb. 6, 2012) ("*Miralax*"); *In re Metoprolol Succinate Direct Purchaser Antitrust Litig*., No. 06-cv-052, 2011 WL 13097266 (D. Del. Nov. 16, 2011) ("*Toprol*"); *In re DDAVP Direct Purchaser Antitrust Litig*., No. 05-cv-2237, 2011 WL 13318188 (S.D.N.Y. Aug. 16, 2011); *In re OxyContin Antitrust Litig*., MDL No. 1603, 2010 WL 11493630 (S.D.N.Y. Sept. 27, 2010); *In re Children's Ibuprofen Oral Suspension Antitrust Litig*., No. 04-mc-535, ECF No. 24 (D.D.C. Jan. 9, 2006); *In re Remeron Direct Purchaser Antitrust Litig.*, No 03-cv-0085, ECF No. 181 (D.N.J. Aug. 30, 2005); *North Shore Hematology and Oncology Assoc.*, No. 04-cv-00248, ECF No. 21 (D.D.C. Sept. 10, 2004). Settlement classes must meet all requirements of Rule 23(a) and (b)(3), except for manageability. *Amchem Prods.*, *Inc. v. Windsor*, 521 U.S. 591, 620 (1997).

[3] *See*, *e.g.*, *Celebrex*, 2017 WL 3669604, at *17-18.

[4] "Merck" refers to Merck & Company, Inc., Merck Sharp & Dohme Corporation, Schering-Plough Corporation, Schering Corporation, and MSP Singapore Company LLC. "Glenmark" refers to Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA. "Par" refers to Par Pharmaceutical, Inc. While Par is also a defendant in this litigation, it has entered a settlement agreement with the direct purchaser class plaintiffs that has been preliminarily approved by the Court and awaits final approval pending a fairness hearing. *See* November 5, 2019 Order Adopting Report and Recommendations, ECF No. 711.

[5] FWK Holdings, LLC ("FWK"), Rochester Drug Co-Operative, Inc. ("RDC"), and Cesar Castillo, Inc. ("Castillo").

entities in the United States or its territories that purchased Zetia or generic Zetia in any form directly from Merck, Glenmark/Par, or any agents, predecessors, or successors thereof from July 1, 2012 until June 11, 2017.[6] The proposed class meets all requirements of Rule 23(a) and 23(b)(3).

First, there are numerous issues common to all class members and analogous, if not identical, to those in other certified cases, including: (1) whether defendants conspired to delay generic competition for Zetia; (2) whether Merck's reverse payment to Glenmark delayed generic competition for Zetia; (3) whether defendants' agreement caused antitrust injury to the class in the form of overcharges; (4) when generic competition would have begun absent defendants' agreement; and (5) the calculation of aggregate class damages. These core common issues predominate over any conceivable individual ones.

Second, the direct purchaser class plaintiffs will prove the class's damages at trial using class-wide evidence and methodologies that do not vary between class members. Evidence of defendants' liability will focus entirely on *defendants'* conduct. Every class member will use the same documents, witnesses, and other evidence to prove that defendants wrongfully conspired to delay the sale of generic Zetia.

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[6] *See* Direct Purchaser Plaintiffs' Amended Consolidated Class Action Complaint ("Compl."), ECF No. 315, ¶ 305. Excluded from the proposed class are defendants Merck, Glenmark and Par, and their officers, directors, management, employees, parents, subsidiaries, or affiliates, and the government of the United States and all agencies thereof, and all state or local governments and all agencies thereof. Compl., ¶¶ 306, 307. The class period alleged in the direct purchaser class plaintiffs' amended complaint began December 6, 2011. The direct purchaser class plaintiffs have revised that date to July 1, 2012. Rule 23(c)(1)(C) expressly provides that a class certification order "may be altered or amended before final judgment[,]" and "[i]t is well-established that a certifying court 'is not bound by the class definition proposed in the complaint.'" *Namenda*, 331 F. Supp. 3d at 210 (quoting *Robidoux v. Celani*, 987 F.2d 931, 937 (2d Cir. 1993)).

The direct purchaser class plaintiffs will also present common evidence of class-wide injury through the testimony of Dr. Jeffrey Leitzinger, an economist with extensive experience in assessing the impact of AB-rated[7] generic drug competition and suppression,[8] and the same expert plaintiffs relied on in *Celebrex*.[9] Utilizing the same methodology he deployed in analogous cases—cases where federal courts relied on his reports to certify nearly identical direct purchaser classes[10]—Dr. Leitzinger will establish that AB-rated generic versions of Zetia would have sold at a fraction of Zetia's price and would have rapidly replaced the brand. Dr. Leitzinger will first establish that all members of the class paid overcharges and will then apply his accepted methodology to calculate aggregate damages for the class.

The direct purchaser class plaintiffs therefore request that the Court certify the class, appoint the named plaintiffs as class representatives, and appoint class counsel.

II. FACTS

A. Common evidence will establish defendants' liability.

Evidence common to every member of the class demonstrates that defendants wrongfully agreed to delay market entry of generic Zetia and thereby forced the direct purchaser class to pay

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[7] The FDA uses the term "AB-rated" to classify a generic drug product that is therapeutically equivalent to its branded counterpart. In most states, an AB-rated generic drug is automatically substituted by pharmacies for a branded counterpart without contacting a physician.

[8] *See* Exhibit 1 to the Declaration of Thomas M. Sobol in Support of Direct Purchaser Plaintiffs' Motion for Class Certification ("Sobol Decl."), Declaration of Jeffrey Leitzinger Ph.D., dated November 18, 2019 ("Leitzinger Decl.") at Exhibit 1 thereto (his CV); *see also* Leitzinger Decl. at ¶ 3 n. 2 (identifying prior experience in cases involving allegations of impaired generic competition for the brand drugs Intunive, Loestrin, Niaspan, Solodyn, Celebrex, Lidoderm, Prograf, Wellbutrin XL, Relafen, Tricor, Ovcon 35, Nifedipine, K-Dur, Arava, and Flonase).

[9] *See Celebrex*, 2017 WL 3669604, at *5.

[10] *See*, *e.g.*, *See, e.g.*, *Solodyn*, 2017 WL 4621777, at *8-10; *Lidoderm*, 2017 WL 679367, at *10-13; *Wellbutrin XL*, 2011 WL 3563385, at *12-16; *K-Dur*, 2008 WL 2699390, at *15-20.

higher prices for Zetia and generic Zetia than they otherwise would have paid during the class period. The common evidence will show that this scheme successfully and unlawfully kept generics off the market and injured the class.

The FDA approved Merck's New Drug Application ("NDA") for Zetia, granting it five years of New Chemical Entity exclusivity on October 25, 2002.[11] Merck then launched Zetia in November.[12] Merck listed several patents that it claimed covered Zetia in the FDA's Orange Book, and further sought to extend its patent protection for Zetia by filing additional patent applications.[13]

On October 25, 2006, one year before the expiration of Zetia's new chemical entity exclusivity, Glenmark filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to sell generic Zetia.[14] Glenmark's ANDA included a "Paragraph IV certification" that all of the Zetia patents then listed in the Orange Book were invalid, unenforceable, and not infringed by Glenmark's product.[15] Glenmark was the first to file a Paragraph IV certification for Zetia, entitling it to 180 days of generic marketing exclusivity during which only Glenmark's generic and Merck's authorized generic ("AG") version of Zetia (if created) could be sold.

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[11] [redacted]

[12] [redacted]

[13] After Merck filed its NDA, but before it was approved, Merck sought to extend its patent protection for Zetia. Merck filed a series of patent applications relating to compounds that inhibit sterol absorption and methods for treating specific conditions with those compounds. Two issued as patents (the '106 patent and the '058 patent) (the "sterol non-absorption" applications and patents) (Compl. ¶ 140).

[14] [redacted]

[15] 21 U.S.C. § 355(j)(2)(A)(vii); [redacted]

Merck sued Glenmark in the District of New Jersey on March 22, 2007, alleging that Glenmark's ANDA infringed only one of Merck's patents (the RE'721 patent).[16] Merck's suit triggered a statutory 30-month stay, during which time the FDA could not approve Glenmark's generic version of Zetia.[17] This stay expired on October 25, 2010.

Merck and Glenmark continued to litigate that case for nearly three years. Then, on April 29, 2010, two weeks before Glenmark and Merck were set to go to trial, Glenmark executed a marketing and distribution agreement with Par.[18] Under that distribution agreement, Par became the "exclusive distributor" of any Glenmark generic ezetimibe product,[19] which Par would purchase from Glenmark at Glenmark's manufacturing cost plus shipping expenses[20] (that is, without any markup). Par was "solely responsible for establishing its selling prices" for generic ezetimibe[21] and any profits from the sale of generic ezetimibe would be split among Par and Glenmark 50/50.[22] Glenmark and Par also agreed that neither party would "enter into a settlement with a third party" related to generic ezetimibe "without the prior written consent of the other Party"[23] and that the two would jointly make "all material decisions" with respect to the Glenmark/Merck patent infringement litigation.[24]

Ten days later and just two days before Merck and Glenmark's patent trial was set to

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[16] *See Schering Corp. v. Glenmark Pharmaceuticals Inc, USA*, 07-cv-01334 (D.N.J. Complaint filed Mar. 22, 2007)

[17] 21 U.S.C. § 355(j)(5)(B)(iii).

[18] Sobol Decl., Ex. 6, GLENMARK-ZETIA-00056715 (Distribution Agreement).

[19] *Id*. at §§ 2.1, 1.48

[20] *Id.* at §§ 4.2.1, 1.54.

[21] *Id*. at § 3.1.

[22] *Id.* at § 5.1.2.

[23] *Id.* at § 9.2.3.

[24] *Id*. at § 9.2.2.

begin, Merck and Glenmark (with Par's participation and approval) entered into a settlement in which Glenmark agreed to delay its launch of its generic version of Zetia until December 2016—more than six years.[25]

In exchange for Glenmark and Par's agreement to delay generic Zetia entry by many years, Merck agreed that it would not compete against Glenmark and Par's generic Zetia product by selling or licensing a less expensive AG version of Zetia during Glenmark's 180-day exclusivity period.[26] This meant that the Glenmark/Par product would be the *only* generic version of Zetia on the market for 180 days (a "no-AG" promise). Merck's agreement was hugely valuable to Glenmark and Par; while the commitment cost Merck substantial AG dollars, the payoff enabled Merck to reap a multi-billion dollar windfall.

Evidence common to the class demonstrates that Glenmark, Merck, and Par[27] understood that their mutually-negotiated agreement precluded Merck from launching an AG during

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[25] Sobol Decl., Ex. 7, GLENMARK-ZETIA-00242734 (Settlement Agreement), § 5.4.

[26] *Id.* at § 5.3.

[27] Sobol Decl., Ex. 30, PAR_00002319, Slide 24 (Internal Par PowerPoint presentation, stating, with regard to ezetimibe, that "[redacted]"); Sobol Decl., Ex. 31, PAR_00004800 (February 29, 2016 email from Paul Campanelli — Par's then President — stating "[redacted]").

Glenmark's 180-day exclusivity period,[28] and that the no-AG promise was valuable.[29] For example, almost immediately after executing the agreement, Glenmark sought to monetize its no-AG asset.[30] In a May 11, 2010 email to potential investors – sent just hours after the execution of the agreement – Mr. Gupta, a Glenmark executive, noted the recent "[redacted]" and advised the investors that "[redacted]" for its generic Zetia product, which would net "[redacted]

[28] Sobol Decl., Ex. 8, MRKZETIA_R000061858 (Feb. 26, 2010 email from Glenmark negotiator Vijay Soni to Merck negotiator Paul Matukaitis: "[redacted]"); Sobol Decl., Ex. 9, GLENMARK-ZETIA-00201568 (May 11, 2010 email from Glenmark negotiator Terrance Coughlin to Glenmark CEO Glenn Saldahna summarizing the "[redacted]" noting "[redacted]"); Sobol Decl., Ex. 10, Hester Dep. 146:25-147:4 ("[redacted]"), 148:3-11 ("[redacted]") (Oct. 15, 2019); Sobol Decl., Ex. 11, Matukaitis Dep. 215:4-14 ("[redacted]"), 217:7-13 ("[redacted]") (Oct. 18, 2019); *see also* Sobol Decl., Ex. 12, MRKZETIA000874087 (June 8, 2016 letter confirming Merck's [redacted]), *and compare with* Sobol Decl., Ex. 13, MRKZETIA000614647 (Glenmark response stating: "[redacted]," and "…[redacted].").

[29] Sobol Decl., Ex. 26, MRKZETIA000510501-504 (January 27, 2016 email chain among T. Salfi, D. Pakula, and G. Dunlop, discussing forecast for Merck AG: "[redacted]"); Sobol Decl., Ex. 19, Pakula Dep. 61:15-21 (same) (Sept. 26, 2019); Sobol Decl., Ex. 27, MRKZETIA000509917 ("[redacted]" showing Net Present Value for AG Zetia of up to [redacted]).

[30] Sobol Decl., Ex. 14, GLENMARK-ZETIA-00261523-24 (May 12, 2010 email from Achin Gupta to Glenn Saldanha regarding "[redacted]").

[redacted]" for Glenmark.[31] Mr. Gupta later confirmed to investors who had executed a confidentiality agreement that Glenmark's [redacted] in generic Zetia sales revenue results from "[redacted]"[32] Despite Glenmark's and Merck's insistence now, having been sued for antitrust violations, that their settlement agreement did not contain a no-AG promise, Merck never did launch an authorized generic of Zetia either on its own or through a third party.

The settlement agreement, which allocated the ezetimibe market between Merck and Glenmark, was extremely valuable to both Merck and Glenmark (which ensured that it would have six months of exclusive generic sales, free from competition from Merck's AG), and extremely harmful to purchasers of ezetimibe. Absent Merck and Glenmark's illegal agreement, generic entry would have occurred much sooner than it did, and as early as July 2012. Absent its promise not to launch an authorized generic version of Zetia in exchange for Glenmark's promise to delay its generic launch, Merck would have launched an authorized generic at or about the same time that Glenmark launched its generic product.[33] As a result, the direct

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[31] Sobol Decl., Ex. 15, GLENMARK-ZETIA-00261530-34 (May 11, 2010 email from Achin Gupta to potential investors.).

[32] Sobol Decl., Ex. 16, GLENMARK-ZETIA-00261273-328 (May 28, 2010 email from Achin Gupta to potential investors attaching "[redacted]" information memorandum). In a March 28, 2015 Opinion Letter prepared by outside counsel for Glenmark, Richard Pettus, a senior Greenberg Traurig shareholder, concluded that: "[redacted]" Sobol Decl., Ex. 17, GLENMARK-ZETIA-00435581 (Summary of Assessment of Ezetimibe Settlement Agreement (dated May 10, 2010)).

[33] In the fall of 2016, as Merck was attempting to negotiate a compromise entry date for its authorized generic, Merck contracted with another company, Prasco to distribute, beginning on or after April 25, 2017, Merck's authorized generic Zetia. Sobol Decl., Ex. 18, MRKZETIA000509809 (October 20, 2016 Merck-Prasco Supply and Distribution Agreement for Authorized Generic Zetia). Merck manufactured and delivered launch quantities of authorized generic Zetia—[redacted]—to a Prasco

purchaser class plaintiffs were forced to pay higher brand prices for Zetia, instead of the lower prices for generic ezetimibe they would have paid otherwise.

B. Common evidence will establish class-wide impact.

Plaintiffs have submitted an expert declaration from Dr. Jeffrey J. Leitzinger, who concludes that common proof shows that defendants' illegal delay of generic Zetia resulted in class-wide impact in the form of overcharges.[34] The common proof includes: (a) academic and government research on the predictable, market-wide effects of generic competition; (b) forecasts and other internal documents from Merck, Glenmark, Par and generic manufacturers analyzing the expected market-wide effects of generic competition for Zetia; (c) the actual experience with generic competition, and (d) class members' economic role as intermediaries in the chain of distribution.[35] Courts have consistently held that such common evidence can prove antitrust impact on a class-wide basis.[36]

Dr. Leitzinger concludes that, if plaintiffs prove that defendants illegally delayed generic competition, then defendants' conduct "very likely would cause each member of the class to incur at least some overcharge and therefore suffer antitrust injury."[37] Dr. Leitzinger demonstrates in his Declaration that he can calculate aggregate class overcharges using common

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distribution warehouse. Sobol Decl., Ex. 19, Pakula Dep. 295:24-296:23; Sobol Decl., Ex. 20, MRKZETIA000511408 (April 19, 2017 Merck/Prasco Supply Team Meeting Minutes); Sobol Decl., Ex. 21, MRKZETIA000510456 (October 19, 2017 email from J. Greenberg to D. Pakula re: Zetia AG Material Disposition).

[34] Leitzinger Decl. at ¶ 10; *see also id.* ¶¶ 23-47. "[T]he Supreme Court long ago recognized in the antitrust context [that] overpayment is a cognizable form of injury." *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 190 (1st Cir. 2009); *see also Lidoderm*, 2017 WL 679367, at *10 (overcharge is a "well-recognized type of antitrust injury").

[35] Leitzinger Decl. at ¶¶ 23-47

[36] *Supra* nn. 1-2 (citing cases).

[37] Leitzinger Decl. at ¶ 23.

evidence and the same methodology he has used in numerous prior cases.[38]

III. ARGUMENT

Class actions play a crucial role in antitrust enforcement.[39] Courts in this district and elsewhere have repeatedly certified direct purchaser classes in similar cases alleging delayed generic competition.[40] This body of law provides a compelling blueprint for certification here. These cases involve analogous classes, fact patterns, legal claims, experts, and requested relief.

Here, the proposed class satisfies all prerequisites of Rule 23(a) and Rule 23(b)(3).[41] To grant certification, a district court must be "satisfied, after a rigorous analysis, that the prerequisites of Rule 23(a) have been satisfied"[42] and must resolve factual disputes necessary to making such a determination,[43] with findings supported by a "preponderance of the evidence."[44] Rule 23 does not, however, grant courts a "license to engage in free-ranging merits inquiries at the certification stage. Merits questions may be considered, to the extent—but only to the extent—that they are relevant to determining whether the Rule 23 prerequisites for class certification are satisfied."[45]

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[38] *Id*. at ¶¶ 48-62.

[39] *Reiter v. Sonotone Corp*., 442 U.S. 330, 343-44 (1979); *Hawaii v. Standard Oil Co*., 405 U.S. 251, 262-66 (1972).

[40] *See supra* nn. 1 & 2.

[41] *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 614 (1997) ("In addition to satisfying Rule 23(a)'s prerequisites, parties seeking class certification must show that the action is maintainable under Rule 23(b)(1), (2), or (3).").

[42] *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350-51 (2011) (citation omitted).

[43] *Brown v. Nucor Corp.*, 785 F.3d 895, 903 (4th Cir. 2015).

[44] *Celebrex*, 2017 WL 3669604, at *5 (citing *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 320 (3d Cir. 2008)).

[45] *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 568 U.S. 455, 466 (2013); *see also Brown*, 785 F.3d at 903.

A. The wide dispersal of direct purchaser settlement class members makes their joinder impractical.

The proposed class here includes 70 members.[46] Rule 23(a)(1) permits class certification if "the class is so numerous that joinder of all members is impracticable." The Fourth Circuit has held that "[n]o specified number is needed to maintain a class action,"[47] and has certified a class numbering only 18 class members even when those class members were all located in the same area.[48] "Generally, classes consisting of forty or more members are considered sufficiently large to satisfy the impracticability requirement."[49] Courts have certified far smaller classes in similar cases.[50]

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[46] Leitzinger Report ¶ 42 n. 67 and Exhibit 8. The 70 member class [redacted] *Id.* at Exhibit 8. On October 15, 2019, Magistrate Judge Miller issued a Report and Recommendation concluding, among other things, that "[w]ith respect to ezetimibe manufactured by Glenmark and sold by Par, [direct purchaser] Plaintiffs are indirect purchasers and therefore lack standing to pursue § 4 damages." ECF No. 698 at 32. The direct purchaser plaintiffs filed their objections to that Report and Recommendation on October 29, 2019. ECF Nos. 706, 707. Those objections have not yet been ruled upon. When they are, the Court's ruling may alter the composition of the direct purchaser class, but, at maximum, [redacted]

[47] *Brady v. Thurston Motor Lines*, 726 F.2d 136, 145 (4th Cir. 1984) (quoting *Cypress v. Newport News Gen. & Nonsectarian Hosp. Ass'n*, 375 F.2d 648, 653 (4th Cir. 1967)).

[48] *Cypress*, 375 F.2d at 653.

[49] *Celebrex*, 2017 WL 3669604, at *6 (citations omitted); *see also Niaspan*, 2019 WL 3816829, at *5 ("[T]he sheer size of the forty-eight member DPP putative class raises a presumption of impracticable joinder and poses a far greater challenge to judicial economy if the case were to proceed through joinder."); *Peoples v. Wendover Funding, Inc.*, 179 F.R.D. 492, 497 (D. Md. 1998) ("[G]enerally, courts find classes of at least 40 members sufficiently large to satisfy the impracticability requirement.").

[50] *See, e.g.*, *Celebrex*, 2017 WL 3669604, at *1 (32 members); *Asacol*, 2017 WL 4118967, at *1 (26 members); *Doryx*, 2014 WL 631031, at *2 (23 members); *Nexium*, 296 F.R.D. at 51 (24-29 members); *Prograf*, 2013 WL 2395083, at *1 (25 members); *Wellbutrin XL*, 2011 WL 3563385, at *3-4 (33 members); *Flonase*, 274 F.R.D. at 133 (33 members); *Ovcon*, 246 F.R.D. at 305-06 & n.14 (30 members); *see also K-Dur*, 2008 WL 2699390, at *3 (collecting cases); *see also Fangman v. Genuine Title, LLC*, No. 14-cv-81, 2016 WL 6600509, at *8 (D. Md. Nov. 8, 2016) ("[A] class consisting of as few as 25 to 30 members raises the presumption that joinder would be impractical." (quoting *Baehr v. Creig Northrop Team, P.C.*, No. 13-cv-933, 2014 WL

Joinder is impracticable in this case because the proposed class is geographically dispersed throughout the country. The class "is comprised of companies of varying size, geographically spread across the United States and Puerto Rico . . . Such geographic dispersion regularly weighs in favor of an impracticability finding."[51] Moreover, widespread "geographic dispersion" "suggests joinder is impracticable, even when putative class members are corporate entities."[52] "The alternative to class certification would be largely duplicative litigation that relied on many of the same witnesses and much of the same evidence necessary to prove this claim."[53] "Individual suits" by these class members—spread across the country in disparate courts—would unnecessarily burden the judicial system. Thus, the class's geographic dispersion renders joinder "an unwieldy prospect."[54]

In addition, joinder here is impracticable because "direct purchasers sometimes may refrain from bringing a treble-damages suit for fear of disrupting relations with their suppliers."[55] Retaliation against plaintiffs has occurred in pharmaceutical antitrust class cases,[56] and certification will help ensure that defendants do not keep ill-gotten gains merely because some

346635, at *8 (D. Md. Jan. 29, 2014))).

[51] *Celebrex*, 2017 WL 3669604, *10; *see also Milbourne v. JRK Residential Am., LLC*, No. 12-cv-861, 2014 WL 5529731, at *5 (E.D. Va. Oct. 31, 2014) (where "class members are not centrally located" and reside in multiple states "[t]his factor weighs in favor of finding numerosity because the nationwide dispersion makes joinder of all plaintiffs an unwieldy prospect").

[52] *Solodyn*, 2017 WL 4621777, at *5.

[53] *Celebrex*, 2017 WL 3669604, at *10.

[54] *Milbourne*, 2014 WL 5529731, at *5 (certifying class of 43).

[55] *Ill. Brick*, 431 U.S. at 746.

[56] *See, e.g.*, *Rochester Drug Corp., Inc. v. Braintree Labs.*, 796 F. Supp. 2d 560, 567 (D. Del. 2011) ("[T]here is no dispute that defendant at bar terminated its business relationship with plaintiffs specifically as a result of plaintiffs' pursuit of [pharmaceutical antitrust] litigation . . . ." (footnote omitted)).

members of the class may be reluctant to sue their suppliers.[57]

Finally, to the extent that members of the class must be "clearly ascertainable,"[58] they are here.[59] The requirements of Rule 23(a)(1) are therefore satisfied.

B. The key issues of law and fact are common to all class members.

Rule 23(a)(2) requires at least one question of law or fact common to the class.[60] "A common question is one that can be resolved for each class member in a single hearing" and does not "turn[] on a consideration of the individual circumstances of each class member."[61] Rule 23(a)(2) does not require that *every* question of fact and law be common to the class. The class's claims "must depend upon a common contention . . . of such a nature that it is capable of classwide resolution" and it should have the capacity to "generate common *answers* apt to drive the resolution of the litigation."[62] Demonstrating commonality does not require proof that the putative class will prevail on whatever common questions it identifies. "Certification is only concerned with the commonality (not the apparent merit) of the claims . . . ."[63]

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[57] *Cf. In re Indus. Diamonds Antitrust Litig.*, 167 F.R.D. 374, 386 (S.D.N.Y. 1996) (holding that a class action was the superior method of adjudicating case where, among other things, some class members "still depend on [the defendants] for their supply of industrial diamond products and may be hesitant to disrupt those relationships"); 6 Herbert B. Newberg & Alba Conte, *Newberg on Class Actions* § 18.41 (4th ed. 2002) ("Class actions perform an important function in cases where individual franchisees or purchasers are reluctant to sue because they fear economic reprisal.").

[58] *See Harris v. Rainey*, 299 F.R.D. 486, 495 (W.D. Va. 2014).

[59] *See* Leitzinger Decl. Exhibit 8 (listing class members).

[60] *Wal-Mart*, 564 U.S. at 350 (commonality requirement is met where claims "depend on a common contention . . . that [] is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke").

[61] *Thorn*, 445 F.3d at 319 (citation omitted).

[62] *Wal-Mart*, 564 U.S. at 350 (quoting Richard A. Nagareda, *Class Certification in the Age of Aggregate Proof*, 84 N.Y.U. L. REV. 97, 132 (2009)).

[63] *Brown*, 576 F.3d at 152 (quoting *Lilly v. Harris-Teeter Supermarket*, 720 F.2d 326, 332-33

"Generally, antitrust plaintiffs are found to have satisfied this element in their complaint as an allegation of conspiracy or monopolization will generally be treated as a 'central' or 'single overriding' issue, or 'common nucleus of operative fact' sufficient to establish a common question." [64] Here, Rule 23(a)(2)'s commonality requirement is readily met. "In the antitrust context, courts have generally held that an alleged conspiracy or monopoly is a common issue that will satisfy Rule 23(a)(2)."[65] The class here alleges injury based on the exact same misconduct that was intended to and did impair generic competition.[66] "Because Plaintiffs have alleged that all of the proposed class members were injured as a result of [defendants'] alleged antitrust violations, common questions of law and fact exist among all class members regarding [defendants'] conduct, which satisfies the commonality requirement of Rule 23(a)(2)."[67] At trial, plaintiffs will prove that defendants wrongfully impaired generic competition and that all class members would have purchased generic Zetia at significantly lower prices absent defendants' misconduct. As outlined in direct purchaser class plaintiffs' Trial Plan, there are numerous other common issues of law and fact, each of which satisfies Rule 23(a)(2). *See* Sobol Decl., Ex. 32.

(4th Cir. 1983)).

[64] *Brown v. Cameron-Brown Co.*, 92 F.R.D. 32, 38 (E.D. Va. 1981).

[65] *Celebrex*, 2017 WL 3669604, at *10 (citing *Ovcon*, 246 F.R.D. at 300; *Wellbutrin XL*, 2011 WL 3563385, at *4).

[66] *See, e.g.*, *Wellbutrin XL*, 2011 WL 3563385, at *13-14 (common issues include whether "defendants engaged in a scheme to delay the entry of less expensive generic versions" resulting in delayed generic entry); *Solodyn*, 2017 WL 4621777, at *3 n.4 (similar); *Lidoderm*, 2017 WL 679367, at *11 (similar); *Relafen*, 218 F.R.D. at 342 (similar); *Wellbutrin SR*, 2008 WL 1946848, at *2 (similar); *TriCor*, 252 F.R.D. at 225 (similar); *K-Dur*, 2008 WL 2699390, at *4-5 (similar); *Nifedipine*, 246 F.R.D. at 368-69 (similar); *Ovcon*, 246 F.R.D. at 300 (similar); *Premarin*, 225 F.R.D. at 213 (similar); *Buspirone*, 210 F.R.D. at 57 (similar); *Cardizem*, 200 F.R.D. at 303-04 (similar).

[67] *Celebrex*, 2017 WL 3669604, at *10.

C. The class representatives' claims are typical of the class.

Rule 23(a)(3) requires that the claims of the named plaintiffs be "typical" of the class. "A plaintiff's claim is typical if it arises from the same event, practice, or course of conduct that gives rise to the claims of other class members, and if the plaintiff's claim is based on the same legal theory as those of the other members."[68] Typicality does not require that named plaintiffs' claims be "identical to" or "co-extensive with" those of the class.[69] The typicality requirement "has been liberally construed by courts . . . [and] in the antitrust context, typicality 'will be established by plaintiffs and all class members alleging the same antitrust violations by defendants.'"[70] If "the claims of the named plaintiffs and putative class members involve the same conduct by the defendant, typicality is established regardless of factual differences."[71]

Courts in similar delayed generic competition cases have found the typicality prong met because, as here, plaintiffs asserted that defendants' conduct had delayed generic competition, resulting in overcharges for themselves and the class.[72] For the same reasons, typicality is met here.

D. The class representatives and class counsel will fairly and adequately protect the interests of the class.

The final requirement of Rule 23(a) is that the proposed class representative "fairly and

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[68] *McLaurin v. Prestage Foods, Inc.*, 271 F.R.D. 465, 476 (E.D.N.C. 2010).

[69] *Nat'l Constructors Ass'n v. Nat'l Elec. Contractors Ass'n*, 498 F. Supp. 510, 545 (D. Md. 1980) (quoting *In re Four Seasons Sec. Laws Litig.*, 59 F.R.D. 667, 681 (W.D. Okl. 1973), *rev'd on other grounds*, 502 F.2d 834 (10th Cir. 1974)).

[70] *Celebrex*, 2017 WL 3669604, at *11 (alterations in original) (quoting *In re Vitamins Antitrust Litig.*, 209 F.R.D. 251, 260 (D.D.C. 2002)).

[71] *Id.* (quoting *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 183-84 (3d Cir. 2001)).

[72] *See, e.g.*, *Celebrex*, 2017 WL 3669604, at *11; *Neurontin*, 2011 WL 286118, at *4; *K-Dur*, 2008 WL 2699390, at *6; *TriCor*, 252 F.R.D. at 226; *Wellbutrin SR*, 2008 WL 1946848, at *3.

adequately protect the interests of the class." "This standard is met 'if the named plaintiff has interests common with, and not antagonistic to, the [c]lass' interests; and . . . the plaintiff's attorney is qualified, experienced and generally able to conduct the litigation.'"[73] The proposed class representatives and class counsel meet both criteria here.

1. There are no conflicts of interest between the proposed class representatives and absent class members.

A proposed class representative is adequate under Rule 23(a)(4) unless it has non-speculative conflicts with absent class members that are "so palpable as to outweigh the substantial interest of every class member in proceeding with the litigation."[74] As this Court recently stated, "[i]n order for a conflict to defeat class certification, the conflict 'must be more than merely speculative or hypothetical,' but rather 'go to the heart of the litigation.'"[75] Where a defendant's actions form the basis of the antitrust claim, "named plaintiffs and their counsel have the same core objectives as would absent class members."[76]

Here, "all of the class members have the same financial incentive for purposes of the litigation."[77] "[B]ecause *Hanover Shoe* sets the amount of the overcharge as plaintiffs' damages,

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[73] *Thomas v. FTS USA, LLC*, 312 F.R.D. 407, 420 (E.D. Va. 2016) (alterations in original) (quoting *In re Se. Hotel Props. Ltd. P'ship Investor Litig.*, 151 F.R.D. 597, 606-07 (W.D.N.C.1993)).

[74] *In re NASDAQ Mkt. Makers Antitrust Litig.*, 169 F.R.D. 493, 514-15 (S.D.N.Y. 1996); *see In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 81 (D. Mass. 2005) ("The conflict that will prevent a plaintiff from meeting the Rule 23(a)(4) prerequisite must be fundamental, and speculative conflict should be disregarded at the class certification stage." (quoting *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 141 (2d Cir. 2001))).

[75] *Celebrex*, 2017 WL 3669604, at *12 (quoting *Gunnells v. Healthplan Servs., Inc.*, 348 F.3d 417, 430-31 (4th Cir. 2003)).

[76] *In re Carbon Black Antitrust Litig.*, No. 03-cv-10191, 2005 WL 102966, at *14 (D. Mass. Jan. 18, 2005).

[77] *K-Dur*, 686 F.3d at 223 (citing *Hanover Shoe, Inc. v. United Shoe Machinery Corporation*, 392 U.S. 481 (1968)).

all of the class members . . . [must] prov[e] that they were overcharged and recover[] damages based on that overcharge."[78] Accordingly, the interests of the class representatives are aligned with those of absent class members.

FWK. FWK Holdings, LLC is the assignee of antitrust claims of pharmaceutical wholesaler Frank W. Kerr Co. Kerr filed for bankruptcy in 2016; FWK purchased Kerr's antitrust claims in the bankruptcy proceeding. Kerr purchased Zetia directly from Merck during the class period and, like all direct purchasers, incurred overcharges as a result of the defendants' anticompetitive conduct.[79] FWK is now pursuing Kerr's antitrust claims by assignment, seeking to recover Kerr's overcharges. FWK thus satisfies the essential condition of adequacy: that it and all direct purchaser class members "share common objectives and the same factual and legal positions [and] have the same interest in establishing the liability of [defendants.]"[80]

The Court should be advised that in another case, *In re Intuniv Antitrust Litigation*, FWK was found not to be adequate.[81] The court rested its determination on first, that Michael Stahelin, FWK's owner, is a longtime friend of Joseph Vanek, one of FWK's lawyers in this case. Mr. Vanek, an experienced antitrust lawyer, also represented Mr. Stahelin in forming FWK and purchasing Kerr's claims, including contributing to the financing for the purchase. And second, that FWK's manager, Thomas Kolschowsky, was not sufficiently engaged in the litigation.[82]

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[78] *Id.*

[79] Sobol Decl., Ex. 22, Kolschowsky Dep. 88:16-89:8, 100:18-21 (Aug. 14, 2019); Sobol Decl., Ex. 23, (Exhibit 15 to the Kolschowsky deposition).

[80] *Ward v. Dixie Nat. Life Ins. Co.*, 595 F.3d 164, 180 (4th Cir. 2010) (alterations in original) (quoting *Gunnells*, 348 F.3d at 430) (class representative adequate despite "uncertain prediction" that class representative could benefit disproportionately from a damages recovery).

[81] 2019 WL 4645502, at *7-8 (D. Mass. Sept. 24, 2019).

[82] *Id.* at *8 ("Considering the close relationship between FWK and class counsel and the Court's assessment that FWK is not engaged in meaningful supervision of this case," the court

While we respectfully disagree with the court's ruling in *Intuniv*, this is a different case. Among other things, *Intuniv* was the first case filed by FWK, shortly after FWK had begun operations and Mr. Kolschowsky had been appointed manager. This case was filed more than a year later. As a result, FWK comes to this case differently situated from in *Intuniv*.

First, as the *Intuniv* court observed, a friendship between a class representative and counsel alone does not impair adequacy.[83] With all financing for purchase of Kerr's claims long repaid, the relationship between Mr. Stahelin and Mr. Vanek is now purely social.[84] Moreover, Mr. Stahelin has no involvement in operations of FWK – he is a passive investor.[85] It is Mr. Kolschowsky, an experienced business lawyer,[86] who manages FWK, as well as other businesses owned by Mr. Stahelin. Mr. Kolschowsky has "[redacted]" Even if Mr. Stahelin "[redacted]" (which has never happened), Mr. Kolschowsky would "[redacted]."[87] In

found FWK not to be adequate.).

[83] *Id.* at *7; *see, e.g.*, *In re TFT-LCD (Flat Panel) Antitrust Litig.*, 267 F.R.D. 583, 594-95 (N.D. Cal. 2010) ("[t]he mere fact of the plaintiffs' familial and business relationships [with counsel] does not create a per se presumption of impropriety or conflict.").

[84] *LaRocque ex rel. Spang v. TRS Recovery Servs., Inc.*, 285 F.R.D. 139, 149 n.20 (D. Me. 2012) (adequacy unimpaired where the relationship between counsel and plaintiff had ended prior to the time of class certification).

[85] *See Intuniv* at *7 (describing FWK as an "investment vehicle"). Thus, for example, Mr. Stahelin played no role in the selection of counsel in this case, *see* Sobol Decl., Ex. 24, Stahelin Dep. 11:6-16 and 80:4-13 (Sept. 10, 2019), or even in the decision to commence this action, Sobol Decl., Ex. 28, Kolschowsky Dep. 131:14-21. Those were Mr. Kolschowsky's decisions.

[86] Sobol Decl., Ex. 28, Kolschowsky Dep. 8:14-24 (practicing law in Illinois since for 30 years, since 1989).

[87] Sobol Decl., Ex. 28, Kolschowsky Dep. 17:9-22.

manager-managed LLC, such as FWK, the manager has sole responsibility for the management and conduct of the company.[88] Thus, any conflict is purely hypothetical.[89]

Second, Mr. Kolschowsky is substantially involved in this case. He spent up to 45 hours on investigation, discovery, and case administration.[90] Mr. Kolschowsky educated himself on Kerr's business by meeting by telephone three times with Kerr's former vice president and head of purchasing.[91] He educated himself on the claims in the case, reading all of the pleadings and conferring with counsel.[92] Mr. Kolschowsky also assisted with discovery in gathering and reviewing documents, verifying interrogatory answers, investigating the subjects of FWK's examination, and providing rule 30(b)(6) deposition testimony.[93] As a class representative, Mr. Kolschowsky is fully aware of his duties to members of the class.[94]

RDC. RDC has been found an adequate class representative in numerous similar delayed generic antitrust cases, including four decisions rendered this year (*Suboxone*, *Intuniv*, *Namenda*, and *Niaspan*). Through cases spanning over a dozen years, RDC has never been found inadequate to serve.[95]

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[88] *800 S. Wells Commercial LLC v. Cadden*, 103 N.E.3d 875, 885 (Ill. App. Ct. 2018).

[89] *Ward*, 595 F.3d at 180 ("[A] conflict will not defeat the adequacy requirement if it is 'merely speculative or hypothetical.'" (quoting *Gunnells*, 348 F.3d at 430)).

[90] Sobol Decl., Ex. 28, Kolschowsky Dep. 130:1-15, 162:23-163:12.

[91] *Id.* at 161:10-162:22.

[92] *Id.* at 126:6-127:7.

[93] *Id.* at 163:19-165:3 (documents); *e.g.*, 86:22-87:1 (interrogatories); Sobol Decl., Ex 25 (notice of 30(b)(6) deposition). The defendants have not questioned the completeness of Mr. Kolschowsky's testimony.

[94] Sobol Decl., Ex. 28, Kolschowsky Dep. 142:2-143:3 ([redacted]).

[95] RDC was a certified class representative in *Aggrenox*, *Asacol*, *Celebrex*, *DDAVP*, *Doryx*, *Intuniv*, *Lamictal*, *Lidoderm*, *Miralax*, *Namenda*, *Niaspan*, *Norvir*, *Ovcon*, *Prandin*, *Solodyn*,

Castillo. Castillo is a family owned and operated wholesaler of pharmaceuticals and health and beauty products headquartered in Guaynabo, Puerto Rico. During the relevant period, Castillo purchased brand Zetia directly from Merck and also purchased generic Zetia.

2. Class counsel is qualified.

The Court has appointed Hagens Berman Sobol Shapiro LLP ("Hagens Berman") as lead counsel and interim class counsel for the proposed direct purchaser class pursuant to Rule 23(g), and additional counsel as an executive committee. [96] In so doing, the Court recognized that Hagens Berman "has the necessary expertise, resources, and experience to represent" the direct purchaser class.[97] Since then, the Court appointed Hagens Berman as lead counsel for the Par Settlement Class.[98] Hagens Berman has worked diligently, harmoniously, and efficiently with both the executive committee and the other plaintiff groups. Hagens Berman easily satisfies Rules 23(a)(4) as well as Rule 23(g), and the Court should reaffirm its prior Orders appointing lead counsel and the executive committee.

E. Common legal and factual questions predominate.

Here, the Class also satisfies Rule 23(b)(3)'s predominance requirement. Predominance requires that "*questions* common to the class predominate, not that those questions will be answered, on the merits, in favor of the class."[99] Rule 23(b)(3) "does *not* require a plaintiff seeking class certification to prove that each 'elemen[t] of [her] claim [is] susceptible to class-

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Skelaxin, *Suboxone*, *TriCor*, and *Nifedipine*. *See*, *supra*, nn. 1-2.

[96] *See* August 15, 2018 Order, ECF No. 105, at 2.

[97] *Id*.

[98] *See* ECF Nos. 668 & 771.

[99] *Amgen*, 568 U.S. at 459 (emphasis added).

wide proof.'" [100] Instead, the rule requires "that common questions 'predominate over any questions affecting only individual [class] members.'"[101] As a result, predominance is "a test readily met in certain cases alleging . . . violations of the antitrust laws."[102] For antitrust claims, plaintiffs must prove three elements: (1) violation of antitrust law; (2) injury and causation; and (3) damages.[103]

Plaintiffs' proof at trial will consist almost exclusively of evidence common to the class. This evidence includes expert testimony on defendants' anticompetitive scheme, classwide antitrust injury and calculation of aggregate damages, as well as testimony and documents from defendants' employees. All of this evidence is common to the class.

1. **Proving antitrust violation presents predominantly common issues.**

As to the first element (violation),[104] courts have held that "[p]roof of the allegedly monopolistic and anti-competitive conduct at the core of the alleged liability is common to the

[100] *Id.* at 469 (alterations in original) (citing Fed. R. Civ. P. 23(b)(3)).

[101] *Id.* (quoting Fed. R. Civ. P. 23(b)(3)).

[102] *Amchem*, 521 U.S. at 625; *see also Cordes & Co. Fin. Servs., Inc. v. A.G. Edwards & Sons, Inc.*, 502 F.3d 91, 108 (2d Cir. 2007).

[103] *See Celebrex*, 2017 WL 3669604, at *13 (citing *Hydrogen Peroxide*, 552 F.3d at 311-12).

[104] Plaintiffs allege that defendants violated Sections 1 of the Sherman Act by entering into an unlawful reverse payment agreement that restrained competition in the market for Zetia and its generic equivalents, and violated Section 2 of the Sherman Act by engaging in a conspiracy to monopolize by entering into the reverse payment agreement. 15 U.S.C. §§ 1, 2. A Section 1 claim has two elements: "(1) a contract, combination, or conspiracy; (2) that imposed an unreasonable restraint of trade." *Robertson v. Sea Pines Real Estate Companies, Inc.*, 679 F.3d 278, 284 (4th Cir. 2012); *United States v. Charlotte-Mecklenburg Hosp. Auth.*, 248 F. Supp. 3d 720, 727 (W.D.N.C. 2017) (same). And a plaintiff alleging a conspiracy to monopolize under Section 2 must demonstrate: (1) a concerted action; (2) specific intent to achieve an unlawful monopoly; (3) commission of an overt act in furtherance of the conspiracy; and (4) antitrust injury. *See Advance Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 150 (4th Cir. 1990); *Virginia Vermiculite, Ltd. V. W.R. Grace & Co.*, 108 F. Supp. 2d 549, 588 (W.D. Va. 2000).

claims of all the plaintiffs" who plead an overcharge theory.[105] Here, the direct purchaser class plaintiffs allege that defendants' scheme delayed generic entry and thereby harmed competition. The conduct wrongfully maintained Merck's monopoly power by (a) suppressing the market entry of AB-rated generic Zetia and thereby (b) ensuring that members of the class were forced to pay more for purchases of ezetimibe than they would have absent the reverse payments.

If they were pursuing this case individually, each class member would have to prove the same course of conduct, using the same documents and witnesses. "Based on this common evidence, the legal issues surrounding the antitrust violation will also be resolved uniformly across the class—whether [defendants] violated antitrust laws does not depend on any legal issue unique to a particular class member. Accordingly, Plaintiffs have proven by a preponderance of the evidence that common issues regarding the antitrust violation predominate over any individualized inquiry."[106] Predominance is therefore satisfied on the issue of antitrust violation alone.[107]

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[105] *Buspirone*, 210 F.R.D. at 58; *see also Namenda*, 331 F. Supp. 3d at 215 ("As to liability, I agree that common questions predominate over the class.").

[106] *Celebrex*, 2017 WL 3669604, at *14.

[107] *See Titanium Dioxide*, 284 F.R.D. at 344 ("[T]he elements of antitrust injury is capable of proof at trial through evidence that is common to the class."); *TriCor*, 252 F.R.D. at 228 ("[E]ach putative class member, had they pursued their claims individually, would have been required to prove identical facts, such as defendants' monopoly power, exclusionary scheme, effect on interstate commerce, conspiracy, and unreasonable restraint of trade. Therefore, these common issues predominate over any individual issues relating to proof of an antitrust violation."); *Flonase*, 274 F.R.D. at 135 ("Direct Purchasers' Section 2 claim requires proof of GSK's actions and intent. Such proof will necessarily be class-wide – GSK's actions did not vary with respect to individual direct purchasers, aside from the price charged . . . . The evidence thus should be identical for all 33 members of the Proposed Class. I find that Direct Purchasers satisfy this prong of the predominance inquiry."); *K-Dur*, 2008 WL 2699390, at *12 ("Courts routinely find that proof of a violation of the antitrust law focuses on the defendants' conduct and not on the conduct of individual class members.").

2. **Proving antitrust injury presents predominantly common issues.**

The direct purchaser class plaintiffs will also offer common proof of antitrust injury or impact.[108] At the class certification stage, the plaintiffs need only "demonstrate that the element of antitrust impact is *capable of proof* at trial through evidence that is common to the class rather than individual to its members."[109] As in similar cases, antitrust injury in the form of an overcharge can be proved through common evidence.

Plaintiffs' expert, Dr. Leitzinger, has concluded that evidence common to the class shows that delay in generic entry caused each class member to suffer antitrust injury.[110] Dr. Leitzinger identifies several types of common evidence that independently and conjunctively support his conclusion that all or nearly all class members paid at least some overcharge. Numerous courts have held similar evidence sufficient to prove antitrust injury on a class-wide basis.[111]

Here, "Dr. Leitzinger's report makes several foundational conclusions regarding the

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[108] *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969).

[109] *Titanium Dioxide*, 284 F.R.D. at 345 (quoting *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311-12 (3d Cir. 2008)).

[110] Leitzinger Decl. at ¶¶ 23-47.

[111] *See, e.g.*, *Namenda*, 331 F. Supp. 3d at 215-16 (holding that studies, defendant's analyses, and sales data were sufficient forms of common proof of antitrust injury); *Solodyn*, 2017 WL 4621777, at *7-8 ("economic research," "forecasting documents," and data are "sufficiently reliable to show common impact"); *Celebrex*, 2017 WL 3669604, at *14-15 (same); *Lidoderm*, 2017 WL 679367, at *9-10 (forecasts and literature are sufficient common proof); *Wellbutrin XL*, 2011 WL 3563385, at *12 (literature, defendants' forecasts, and sales data are sufficient common proof); *Neurontin*, 2011 WL 286118, at *6-8 (literature, defendants' analyses, and sales data are "well established" forms of common evidence); *Flonase*, 274 F.R.D. at 136 (E.D. Pa. 2010) (literature, defendants' analyses, and sales data are sufficient); *Norvir*, 2008 WL 4065839, at *8-9 (same); *Tricor*, 252 F.R.D. at 229-30 (studies and empirical evidence "can demonstrate impact on a class-wide basis"); *Wellbutrin SR*, 2008 WL 1946848, at *8 ("[L]iterature examining the impact of generic entry into the pharmaceutical market and analysis of public data."); *K-Dur*, 2008 WL 2699390, at *14-19 (studies, defendants' analyses, and sales data sufficient forms of common evidence); *Nifedipine*, 246 F.R.D. at 370-71 & n.10 (same); *Ovcon*, 246 F.R.D. at 308-10 (same); *Relafen*, 218 F.R.D. at 343-46 (same); *Premarin*, 225 F.R.D. at 217-218 (same); *Buspirone*, 210 F.R.D. at 58 (same); *Cardizem*, 200 F.R.D. at 308 (same).

market for generic pharmaceutical drugs that are relevant to the issue of antitrust impact."[112] First, Dr. Leitzinger reviews extensive empirical economic research concluding that generics quickly replace brands at substantially lower prices, with generic prices falling even further as the number of generic competitors increases.[113] For example, the Federal Trade Commission found that one year after generic entry, generics captured, on average, *90% of brand sales*. The same FTC report found that generics prices were *85% lower* than brand prices.[114] This research demonstrates the robust pro-competitive impact of unimpaired generic entry and is strong common evidence of class-wide impact here.

Second, Dr. Leitzinger cites forecasts and other documents prepared by Merck, Glenmark and non-party generic manufacturers concluding that generic Zetia would follow this same pattern, quickly capturing most brand sales at lower prices, with generic prices falling as the number of generic competitors increases.[115] These forecasts constitute common, class-wide evidence that delayed generic competition causes overcharges by preventing purchasers from accessing the savings that unimpaired generic competition offers.

Third, Dr. Leitzinger considers what actually happened following the belated launch of generic Zetia. The data produced by defendants and the generic manufacturers show that prices fell for virtually all class members after generic entry, either from substitution of the cheaper generic for the brand, and/or getting increased discounts on the generic when there were six

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[112] *Celebrex*, 2017 WL 3669604, at *14.

[113] Leitzinger Decl. at ¶¶ 24-30.

[114] Sobol Decl., Ex. 28, Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010); *see also* Sobol Decl., Ex. 29, IMS Consulting, *Report to PhRMA, Assessment of Authorized Generics in the U.S.* 16 (2006) (finding that the generic discount to the brand price was sixteen percent larger when there was authorized generic in the market, and that the larger generic price discount continued after the exclusivity period).

[115] *Id.* at ¶¶ 31-35.

generics on the market instead of one.[116] This actual market experience confirms what is predicted in the literature and in the forecasts: prices fell marketwide, *for all or nearly all direct purchasers*, following generic entry and fell even more with an additional generic on the market. This classwide evidence is capable of proving classwide injury.

Finally, Dr. Leitzinger concludes that because class members are intermediaries in the chain of pharmaceutical distribution, there is no reason to think that any class member—whether a wholesaler or retailer—exclusively served a small enough fraction of the prescription base such that the class member would not benefit from generic competition.[117]

Courts have repeatedly found that these kinds of common evidence can sufficiently establish classwide antitrust impact through predominantly common proof.[118] Because the issue of antitrust impact will be proved at trial with evidence that is predominantly or entirely common to the class, rather than individual to its members, and because that evidence shows that all or virtually all class members suffered antitrust impact from defendants' challenged conduct, the predominance standard is met here.

3. Proving class-wide damages presents predominantly common issues.

The predominance requirement is further satisfied where, as here, experts can readily measure aggregate damages to the class using common evidence and a common methodology.[119]

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[116] *Id*. at ¶¶ 43, 46

[117] *Id.* at ¶¶ 23, 39.

[118] *See supra* nn. 1 & 2; *Celebrex*, 2017 WL 3669604, at *15.

[119] *See, e.g.*, *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 535 (6th Cir. 2008) (approving Dr. Leitzinger's use of class-wide aggregate damage model); *Kleen Products LLC v. Int'l Paper Co.*, 831 F.3d 919, 929 (7th Cir. 2016) ("[A]t the class certification stage, plaintiffs are not obliged to drill down and estimate each individual class member's damages. The determination of the aggregate class-wide damages is something that can be handled most efficiently as a class action, and the allocation of that total sum among the class members can be managed individually."); *Namenda*, 331 F. Supp. 3d at 177-81 (approving aggregate damages); *Solodyn*,

Importantly, "a defendant whose wrongful conduct has rendered difficult the ascertainment of the precise damages suffered by the plaintiff, is not entitled to complain that they cannot be measured with the same exactness and precision as would otherwise be possible."[120] "Calculations need not be exact," though "any model supporting a plaintiff's damages case must be consistent with its liability case."[121]

The possibility of individual damages inquiries does not pose an obstacle to certification.[122] Courts have certified similar classes alleging suppressed generic drug competition despite defense arguments that individual damage questions and "variations" in prices and rebates preclude certification.[123] That members of the class suffered varying amounts of damage is also no bar to certification.[124]

2017 WL 4621777, at *10 (same); *Celebrex*, 2017 WL 3669604, at *16 (same); *Lidoderm*, 2017 WL 679367, at *11 (same).

[120] *Eastman Kodak Co. v. S. Photo Materials Co.*, 273 U.S. 359, 379 (1927); *see also Spray-Rite Serv. Corp. v. Monsanto Co.*, 684 F.2d 1226, 1243 (7th Cir. 1982) (same). Damages may be estimated from available evidence. *See Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563 (1931); *Solodyn*, 2017 WL 4621777, at *10 ("[A]lthough Plaintiffs bear the burden to establish predominance, uncertainties regarding damages should be resolved against the wrongdoer, and not those who have allegedly been injured.").

[121] *Comcast*, 569 U.S. at 35 (citations omitted); *see also Kleen*, 831 F.3d at 929 (rejecting argument that class plaintiffs must show individual and not aggregate damages as a matter of law and holding that "plaintiffs are permitted to use estimates and analysis to calculate a reasonable approximation of their damages"); *Celebrex*, 2017 WL 3669604, at *16 ("Damages calculations need not be exact, but must still be consistent with the theory of liability.").

[122] *See, e.g.*, *Celebrex*, 2017 WL 3669604, at *16 ("The fact that individualized inquiry may be necessary to allocate those damages will not defeat class certification." (citing *Cardizem*, 200 F.R.D. at 348)); *Titanium Dioxide*, 284 F.R.D. at 349 ("The need to inquire into individual damages calculations . . . is not an impediment to class certification.").

[123] *E.g.*, *Celebrex*, 2017 WL 3669604, at 16; *Lidoderm*, 2017 WL 679367, at *11 (variation in direct purchasers' prices paid and damages amounts no bar to certification); *K-Dur*, 686 F.3d at 221-22; *Cardizem*, 200 F.R.D. at 318 (similar); *Flonase*, 274 F.R.D. at 134 (similar); *Nexium*, 296 F.R.D. at 57-58 (similar); *Nifedipine*, 246 F.R.D. at 370 (similar); *Ovcon*, 246 F.R.D. at 312 (similar); *Wellbutrin XL*, 2011 WL 3563385, at *12 (similar).

[124] *See, e.g.*, *In re TD Bank, N.A. Debit Card Overdraft Fee Litig.*, 325 F.R.D. 136 (D.S.C.

In his report, Dr. Leitzinger explains that he will use the same basic methodology that he has used many times before—the one multiple courts approved in similar cases[125]—to measure aggregate class damages.[126] Dr. Leitzinger's model satisfies *Comcast*'s requirement that evidence of damages "measure[s] only those damages attributable to [the] theory"[127] of liability and harm advanced by the direct purchasers—namely, the unlawful delay in generic competition defendants' actions caused.

2018) ("Rule 23(b)(3) is normally satisfied where there is an essential common factual link, such as standardized documents and practices, even though the nature and amount of damages may differ among class members."); *In re Serzone Prods. Liab. Litig.*, 231 F.R.D. 221, 238 (S.D. W. Va. 2005) ("Damage levels vary among the class representatives as they do among members of the class, but all are similarly aggrieved by BMS's conduct, and all assert similar claims of liability."); *McGlothlin v. Connors*, 142 F.R.D. 626, 633 (W.D. Va. 1992) ("[S]ome factual variations between the class members," such as "the amount of damages suffered," "is not fatal to a finding that the predominant legal claims are similar."); *Haywood v. Barnes*, 109 F.R.D. 568, 583 (E.D.N.C. 1986) ("The fact that the potential amount of damages might vary individually with the number of violations does not preclude class certification where common questions of law and fact as to liability clearly predominate. This argument has been rejected time and again by the courts in a multitude of factual settings.").

[125] *See, e.g.*, *Solodyn*, 2017 WL 4621777, at *9-10 (finding that Dr. Leitzinger has "sufficiently shown that damages may be demonstrated by a 'common methodology' applicable to the class as a whole" where plaintiffs assert "that aggregate damages to the Class can be reliably measured using Class-wide evidence . . . and present [their expert's] 'formulaic model' that establishes aggregate overcharges incurred by the putative class") (citation and internal quotation marks omitted); *Lidoderm*, 2017 WL 679367, at *10 (rejecting defendants' critiques of Dr. Leitzinger's "aggregate damages model" as allegedly "unreliable because it fails to consider the 'actual experience' of particular [class members] since it is based on aggregated purchases" and finding that "aggregate approach to damages is not problematic"); *Prograf*, 2013 WL 2395083, at *3 (concluding that "[o]n the issue of damages, the Declaration of Jeffrey J. Leitzinger, Ph.D., together with prior decisions granting class certification . . . , provide the basis for the Court to find that it will be feasible to calculate aggregate damages to the Direct Purchaser Class as a whole using well-established methodologies, including the 'before and after' method"); *Wellbutrin XL*, 2011 WL 3563385, at *14-15 (approving Dr. Leitzinger's damages calculation and certifying the class); *K-Dur*, 2008 WL 2699390, at *19 ("Defendants do not dispute that the 'before and after' methodology proposed by Dr. Leitzinger is 'judicially recognized and commonly accepted.'") (citation omitted).

[126] Leitzinger Decl. at ¶¶ 48-62.

[127] *Comcast*, 569 U.S. at 35.

Dr. Leitzinger explains that, to calculate class overcharges, he will use and rely only on evidence that is common to the class. Overcharges from the delay of generic Zetia competition can be calculated on an aggregate, class-wide basis, using a "before/after" "benchmark" method using the actual market experience with branded and generic Zetia following the belated launches of generic Zetia, by "backcasting" (a) the generic penetration (i.e., generic substitution) rate that would have occurred had generic entry occurred on July 1, 2012 or later; (b) the generic price discount off of the price of branded Zetia had generics launched on July 1, 2012 or later, and (c) the price of branded Zetia had generic competition occurred sooner. This type of benchmark approach is an accepted method of calculating aggregate class-wide damages in antitrust class actions,[128] and is consistently approved by courts in cases involving suppression of generic competition.[129]

F. A class action is superior to other methods of adjudication.

Here, the class action mechanism is superior to other forms of adjudication. The "superiority" requirement of Rule 23(b)(3) ensures that a class action will "achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated,

[128] *See, e.g.*, *In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, No. 02-cv-1486, 2006 WL 1530166, at *8-10 (N.D. Cal. June 5, 2006) (approving expert's "benchmark" and "yardstick" analysis as "a valid methodology"); *In re Rubber Chems. Antitrust Litig.*, 232 F.R.D. 346, 354 (N.D. Cal. 2005) (certifying class where plaintiffs' expert measured class damages with a "benchmark" or "yardstick" approach); *In re Citric Acid Antitrust Litig.*, No. 95-1092, 1996 WL 655791, at *7 (N.D. Cal. Oct. 2, 1996) ("before and after" "benchmark" approach "sufficient to show that means exist for proving impact on a class-wide basis").

[129] *E.g.*, *Lidoderm*, 2017 WL 679367, at *12 (Dr. Leitzinger); *Provigil*, 309 F.R.D. at 212-14 (Dr. Leitzinger); *Wellbutrin XL*, 2011 WL 3563385, at *12-16 & n.7 (Dr. Leitzinger); *Wellbutrin SR*, 2008 WL 1946848, at *8-9; *TriCor*, 252 F.R.D. at 231 (Dr. Leitzinger); *K-Dur*, 2008 WL 2699390, at *14-15 (Dr. Leitzinger); *Nifedipine*, 246 F.R.D. at 371 (Dr. Leitzinger); *Ovcon*, 246 F.R.D. at 310-12 (Dr. Leitzinger).

without sacrificing procedural fairness or bringing about other undesirable results."[130] As demonstrated above, this case present numerous common issues and evidence. Certification avoids clogging the court with numerous individual suits (for those who can afford to sue), prevents inconsistent results, and ensures that class members with smaller claims have an opportunity for redress. In prior cases alleging suppressed generic drug competition, courts have found that a class action was the superior method of adjudicating the case.[131] Certification here would avoid numerous duplicative individual suits. Thus, class action treatment here—just as in the prior analogous cases—is the superior method of adjudicating the plaintiffs' claims and ensuring injured class members recoup their antitrust overcharges.[132]

IV. CONCLUSION

For the foregoing reasons, the direct purchaser class plaintiffs respectfully request the Court certify the proposed class under Fed. R. Civ. P. 23(b)(3).

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[130] *Amchem*, 521 U.S. at 615 (citation omitted).

[131] *See supra* nn. 1-2.

[132] *See, e.g.*, *Celebrex*, 2017 WL 3669604, at *17 ("[I]n the complex context of delayed generic entry the benefits of Rule 23 have been widely recognized." (citing *Ovcon*, 246 F.R.D. at 314; *Relafin*, 218 F.R.D. at 347; *K-Dur*, 2008 WL 2699390, at *21)).

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CERTIFICATE OF SERVICE

I hereby certify that on November 18, 2019, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing (NEF) to all counsel of record who have made a formal appearance.

Dated: November 18, 2019

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